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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,132	05/29/2001	Knut E. Rasmussen	01-11 US	9635
7590 02/24/2004				
Varian Inc 3120 Hansen Way M S D 102 Palo Alto, CA 94304		EXAMINER PADMANABHAN, KARTIC		
		ART UNIT PAPER NUMBER 1641		
DATE MAILED: 02/24/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/857,132

Applicant(s)

RASMUSSEN ET AL.

Examiner

Kartic Padmanabhan

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Priority

1. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 371 as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)).

Claim Objections

2. Claims 21 and 31 objected to because of the following informalities: in both claims, applicant should insert the word "An" at the beginning of the claims. In addition, in line 7 of claim 1, applicant should change "a acceptor" to "an acceptor." Appropriate correction is required.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
6. Claims 21-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rasmussen et al. (WO 97/25606) in view of Berg (US Pat. 6,164,144) and Shindo et al. (US Pat. 4,268,279).

Rasmussen et al. teach a device and method for liquid-liquid microextraction. The method comprises providing a carrier, modifying the carrier, immobilizing a solvent (acceptor solution) on the carrier surface, contacting the carrier with the sample (which may be in solution), concentrating and fixing the analyte of interest to the solvent, and analyzing the carrier. Preferably, a fiber is used as the carrier. The fibers for use with the invention may be made of porous polymers such as polyacrylate. The amount of solvent to be immobilized on the solvent is in the range of 1-5 ul (page 4). The carrier with immobilized solvent is inserted into the sample solution, where the pH may be altered to favor partitioning of analyte and solvent (page 5). The solvent of the reference is preferably a high boiling solvent, such as octanol (page 5). In one embodiment, the fiber is withdrawn into the needle of a syringe, and the needle is used to penetrate the septum of a solvent vial, at which time the fiber is lowered and solvent is immobilized. The fiber is then withdrawn back into the needle and used to penetrate the sample

vial. After the fiber is lowered into the vial, analytes are partitioned by agitating the vial (page 7). Since the fiber only accommodates 1-5 ul of sample, it is inherent that the sample vial has a volume greater than 50X this amount. The sample solution for use with the invention may be plasma. However, the reference does not specifically teach the use of a hollow fiber permeable to analyte or an acidified acceptor solution.

Berg teaches methods and device for solid phase microextraction (SPME). The reference teaches the use of a hollow fiber with SPME, wherein the fiber acts as a “sponge”. In addition, the reference also teaches the use of a magnetic stirring bar as the means of agitation of a sample in a vial. However, neither Rasmussen nor Berg teach the permeability of the hollow fiber to analyte.

Shindo et al. teach a process comprising allowing a liquid to contact the inside of a microporous hollow fiber and a fluid to contact the outside, wherein gaseous components contained in the fluids are allowed to permeate inside and outside of the fiber (abstract).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use a magnetic stirring bar, a hollow fiber permeable to analyte, and an acidified acceptor solution as taught by Berg and Shindo et al. with the invention of Rasmussen et al. By using a hollow fiber, one would have been able to fill the fiber with acceptor solution rather than immobilizing the solution on the surface of the fiber. With such an arrangement, partitioning will occur between analyte and acceptor within the porous fiber, at which time acceptor solution with analyte can be removed and analyzed. Alternatively, if desired, one could have also allowed analyte to permeate through the other side of the fiber before collection for analysis. One would have been able to use this arrangement with a reasonable expectation that it would

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provide results similar to those when acceptor is immobilized on the surface of the fiber.

Depending on the analyte of interest, one of ordinary skill in the art would have had a reasonable expectation of success in selecting hollow fibers with pores of the required size such that analyte would be permeable to the desired analyte. In addition, as taught by Shindo et al., hollow fibers permeable to analytes have been conventionally used in separation or extraction procedures. It would have further been obvious to use a magnetic bar as the stirring means to establish extraction equilibrium (partitioning between sample and acceptor) for the analyte because magnetic stirring bars are very well known in the art for use when agitation is necessary, as taught by Berg et al. One would have had a reasonable expectation of success in using a stirring bar as the agitation means with the method of Rasmussen et al. because both Berg and Rasmussen et al. are drawn to extraction methods and one would have recognized that any agitation means could have been used with the method and device of Rasmussen et al. Furthermore, it would have been obvious to acidify the acceptor solution of Rasmussen et al. because Diazepam, the analyte of interest in Example 1, has its highest partition coefficient at an acidic pH. Finally, it would have also been obvious to modify the method and device of

Rasmussen et al. by using a sponge instead of a fiber as the disposable container. Since Berg teaches that the fiber of the method acts as a sponge, one would have had a reasonable expectation of success in carrying out the method of Rasmussen et al. with the replacement of the fiber with a sponge material. In addition, although Berg deals with solid phase microextraction, the teaching of Berg would have been applicable to the modified method of Rasmussen et al. because Rasmussen et al. use a SPME fiber in their liquid-liquid microextraction method (page 10).

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Response to Arguments

7. Applicant's arguments with respect to claims 21-58 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Claims 21-58 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kartic Padmanabhan whose telephone number is 571-272-0825.

The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kartic Padmanabhan
Patent Examiner
Art Unit 1641

KP


LONG V. LE
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02/06/04